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| DocTitle: | Ventilair II Section 9: 510(k) Summary | DocVersion: | 1.1 |

9 510(K) SUMMARY

1. Summary Preparation Date: January 18, 2005

2. Applicant Information:

Name:

Hamilton Medical AG

Via Nova

CH-7403 Rhäzüns

Switzerland

FDA Establishmen Registration Number: 3001421318 Contact Person: J. David Thompson, General Manager

> Hamilton Medical Inc. P.O.Box 30008 Reno, NV 89502 Phone 775-858-3200 Fax 775-856-5621

Email: thompson@hammed1.com

3. Device Proprietary Name: VENTILAIR II Medical Air Compressor

Common/Usual Name: Air Compressor

Classification Name: Compressor, Air, Portable

Classification Panel: Anesthesiology

Classification Code: BTI

- 4. BTI Device Identification Code (per 21 SFR Part 868.6250): A portable air compressor is a device to provide comopressed air for medical purposes, e.g. to drive ventilators and other respiratory devices.
- 5. Regulatory Status: Portable air compressors and their accessories (FDA product code BTI) have been classified by the FDA as class II. There are currently no mandatory performance standards or special control requirements for these devices.
- 6. Intended Use: The Hamilton Medical VENTILAIR II is intended for use in hospitals and other institutions as an alternative to central air or cylinder air to supply medical air at 30 psi nominal to the GALILEO and the RAPHAEL models of Hamilton Medical ventilators which are intended to be operated with 30 psi nominal medical air supply. It can also be used as a backup medical air supply for these ventilators in case of failure of their normal air supply.
- 7. General Device Description: The VENTILAIR II is an electromechanical and pneumatic device only and has no software-based components. The device is rated at 115 V \pm 10 %, 60 Hertz. It requires 466 Watts to power. The enclosure is designed to be mounted either on the GALILEO model or RAPHAEL model ventilator carts.

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Only one control is accessed during normal device operation, a power switch. The Power switch is switched ON both when the VENTILAIR II is configured and operated as a permanent air supply and when it is used as an emergency backup air supply. An indicator is provided to inform the user of the device performance status. This "Performance Gauge" is a pressure gauge calibrated for three zones of operation: Green (Normal Dry Operation), Yellow (Poor Drying Effect), and Red (Wet with Low Output Pressure).

The VENTILAIR II has two air movements. The first is the cool, clean, dry compressed air movement that provides condensation-free compressed air to the ventilator. The second is the ambient air movement – an S-pattern that cools the entire drying system and compressor within the enclosure.

The VENTILAIR II has been designed for easy maintenance. The compressor air intake filter element must be checked weekly. The 5 micron filter in the water trap must be replaced annually. Two internal pressure regulators and two other internal components must be checked annually and adjusted if necessary. Compressor overhaul is required periodically using the compressor manufacturer's overhaul kit. If the VENTILAIR II is used as an independent or continuous air source, an annual overhaul is recommended. If the compressor is used only as a backup in case of failure of the main air supply, overhaul is recommended every five years. All maintenance and overhaul procedures are described in detail in the VENTILAIR II Operator's and Service Manuals.

The VENTILAIR II is in full compliance with all required safety aspects of the current edition of IEC 60601-1. Several specific safety mechanisms have been incorporated into the VENTILAIR II

- 8. Device Materials: All materials within the VENTILAIR II flow path have been carefully selected to avoid any contamination of the medical air flow path. There are no plastic mold release compounds and no outgassed toxic material present to contaminate the gas flow. A 5 micron filter has been built into the device to capture any particulate impurities. In addition all Hamilton Medical GALILEO and RAPHAEL ventilators have a 0.5 micron filter built into their air inputs to trap any particulate impurities.
- Substanital Eqiuvalence: The Hamilton Medical VENTILAIR II Medical Air Compressor is substantially equivalent to the Draeger Medical Air Compressor (K982789), Infrasonics Air Star Portable Compressor (K920954), and the Bennett MC-2 Mobile Air Compresor (Pre-Amendment).

Among the information presented in the 510(k) submission to support the equivalency of the VENTILAIR II to these predicate devices is: (a.) device description, (b.) comparison to the legally marketed predicate devices, and (c.) laboratory performance verification and validation test data.

10. Comparison Table: The table that follows describes some Important characteristics of the VENTILAIR II Medical Air Compressor and its predicate devices: Draeger Medical Air Compressor (K982789), Infrasonics Air Star Portable Compressor (K920954), and Bennett MC-2 Mobile Air Compressor (Pre-Amendment).

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Comparison to Legally Marketed Predicate Devices

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|--|----------|------------------|---------------------------------|--------------------------|----------------------------|-----------------------------|
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| units, respiration units and other devices requiring other devices requiring clean filtered air controls/visual gauge controls/visual gauge auge indicators Alarms Audible and visual power fallure and low pressure built into ventilator (respiration unit) Filtering Filtering Mater trap (inter, are trap filter (size unspecified in available labeling) Water trap Yes, with automatic vaporization bressure relief Yes, set to 60 PSIG Yes, set to 60 PSIG SIG SIG PSIG SIG Pressure relief Pressure relief Pressure not available pressure Audible and visual power Audible and visual high Audible and visual power fallure and low pressure output air temperature fallure and low pressure relief Yes, with automatic vaporization (respiration unit) Pressure relief Yes, with automatic vaporization vaporization (respiration valve) Pressure relief Yes, set to 60 PSIG SIG SIG SIG SIG SIG SIG SIG SIG SIG | | applications | for Bennet IPPB therapy | compressed air source to | compressed air source to | psi compressed air |
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| clean filtered air User Controls/visual indicators Audible and visual power fallure and low pressure built into ventilator (respiration unit) Filtering Firer, water trap filter (size unspecified in available pressure relief Yes, with automatic vaporization Pressure relief Yes, set to 60 PSIG Auto backup Feature not available Auto backup Clean filtered air Clean filtered | | | other devices requiring | ventilators | Star and other ventilators | GALILEO and RAPHAEL |
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| Pressure relief Yes, set to 60 PSIG Yes, set to 59 PSIG Yes, set to 85 PSIG valve Auto backup Feature not available On at 40.5 PSIG, off at 55 PSIG pressure | ဟ | Water trap | Yes, with automatic | Yes, with automatic | Yes, with automatic | Yes, with automatic |
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| Auto backup Feature not available On at 40.5 PSIG, off at Optional featue, on at 45 pressure PSIG, off at 55 PSIG | 9 | Pressure relief | Yes, set to 60 PSIG | Yes, set to 59 PSIG | Yes, set to 85 PSIG | Yes, set to 32 PSIG |
| Auto backup Feature not available On at 40.5 PSIG, off at Optional featue, on at 45 pressure PSIG, off at 55 PSIG | | valve | | | | |
| 50 PSIG PSIG PSIG off at 55 PSIG | _ | Auto backup | | On at 40.5 PSIG, off at | Optional featue, on at 45 | On at 30 PSIG, off at 38 |
| | | pressure | | 50 PSIG | PSIG, off at 55 PSIG | PSIG |

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| | | | PREDICATE DEVICES | | VENTILAIR II |
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| # | Characteristic | Bennett MC-2 Air | Draeger Medical Air | Infrasonics Air Star | Similar or Different |
| | | Compressor (Pre- | Compressor (K982789) | Compressor (K920954) | (From All Other |
| | | Amendment) | | | Predicates Combined) |
| ۵ | Electrical ratings | 115 V; 60 Hertz; power | 110 V; 60 Hertz; 500 W | 102 to 132 V; 60 Hertz; | 115 ± 10 %; 60 Hertz; |
| | | consumption unspecified | | power consumption | 466 W |
| | | in available labeling | | unspecified in available | |
| | | | | labeling | |
| _. ග | Overcurrent | Unspecified in available | Fuse | Circuit breaker | Fuse |
| | protection | labeling | | | |
| 9 | Output | 45 I/min at 50 PSIG | 30 I/min at 44 PSIG | 55 I/min at 50 PSIG | 40 l/min at 30 PSIG |
| 11 | Dew point | Unspecified in available | 5 °C below room | > 3 °F below room | 3.3 °C below room |
| | depression | labeling | temperature at 30 l/min | temperature at 55 l/min | temperture at 40 l/min |
| 12 | Inputoutput | Two DISS 9/16" - 18 | Quick connect DISS | % - 16 male DISS | %" - 16 male DISS fitting |
| | interrace | threaded outlets (one | coupling with internal | fitting with internal check | with internal check valve |
| | | capped when not in use) | check valve (1 input, 1 | valve (optional input, 1 | (1 input, 1 output) |
| | | | output) | output) | |
| 13 | Ambient | Unspecified in available | 50 to 104 °F; 30 to 95 % | 20 to 95 °F; ≤ 99 % | 50 to 104 °F; < 85 % RH; |
| | environment | labeling | RH, 13,000 ft max. | noncondensing RH; | 7,200 ft maximum altitude |
| | | | altitude | attitude unspecified in | |
| | | | | available labeling | |
| 4 | Noise level | Unspecified in available | 46 to 49 dB(A) | < 55 dB(A) | < 50 dB(A) |
| | | labeling | | | |

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Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

MAR 1 4 2005

Hamilton Medical AG C/O Mr. J. David Thompson General Manager Hamilton Medical, Incorporated P.O. Box 30008 Reno, Nevada 89502

Re: K041781

Trade/Device Name: Hamilton Medical VENTILAIR II Medical Air Compressor

Regulation Number: 868.6250

Regulation Name: Portable Air Compressor

Regulatory Class: II Product Code: BTI Dated: January 27, 2005 Received: January 28, 2005

Dear Mr. Thompson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin. Ph.D

Director

Division of Anesthesiology, General Hospital, Infection Control and Dental Devices Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

| Project N | Name: Ventual:III 510(x) Sübmission HAMIL ION MEDICAL AG | | E37204 |
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| 1 | INDICATION FOR USE STATEMENT | | |

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| 1 INDICATION | ON FOR USE STATEM | ENT | |
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| 510(k) Number (if k | nown) <u>K041781</u> | | |
| Device Name: | Hamilton Medical VENTIL | AIR II Medical Air Com | pressor |
| ndications For Use | : | | |
| alternative to centra RAPHAEL models nominal medical air | al air or cylinder air to supply of Hamilton Medical ventila | medical air at 30 psi r itors which are intend | ils and other institutions as an nominal to the GALILEO and the led to be operated with 30 psi air supply for these ventilators in |
| | | | |
| | | | |
| | | | |
| | | | |
| Prescription Use:_ (Part 21 CFR 801 S | | AND/OR | Over-The-Counter Use (21 CFR 807 Subpart C) |
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| | Concurrence of CDRH, O | ffice of Device Evaluat | ion (ODE) |
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